International and National Regulatory Issues on Access and Benefit Sharing and implications for Material Transfer Agreements

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INTERNATIONAL REGULATION

- Before 1992, the Genetic Resources (GR) were freely accessible and exchanged (with consent of the Supplier and with or without contract);

- In 1992 the Convention on Biological Diversity (CBD) recognized the sovereign rights of States over their natural resources, and the access to GR is subject to national legislation (Art 15.1).

INTERNATIONAL REGULATION

- In 2010 the Nagoya Protocol completed the CBD.
- To assure food security and sustainable agriculture, the International Treaty on Plant Genetic Resources for Food and Agriculture was adopted in 2001:
  - 64 species and genus of plants are concerned
  - A Multilateral System of access and benefit-sharing is established under then management of FAO

CONDITIONS FOR ACCES

- Access to GR shall be
  - o subject to the prior informed consent (PIC) of the Party providing such resources (country of origin of such resources or a Party that has acquired the GR in accordance with the CBD);
  - o on mutually agreed terms (MAT);
- Access to **Traditional Knowledge** (TK) associated with GR is subject to the same procedures, but with the participation of the holders of such knowledge (NP art.7)

FAIR & EQUITABLE BENEFIT-SHARING

- Advantages arising from the utilization of GR shall be shared in a fair and equitable way with the Party providing such resources. Such sharing shall be upon mutually agreed terms.
- The advantages arising from the utilization of TK associated with GR have to be shared in a fair and equitable way with indigenous and local communities holding such knowledge upon MAT.

FAIR & EQUITABLE BENEFIT-SHARING

- The advantages can be monetary or not monetary.
- CIRAD promotes **non monetary** advantages (research collaboration, training, transfer of technology, co-publication, co-property of the results, capacity building…)
- ABS could be a tool to dynamize research collaboration.

PARTIES TO TREATIES

Country	CBD	Nagoya:Signed / Party		ITPGRFA
Australia	1993-06-18	2012-01-20		yes
Bangladesh	1994-05-03	2011-09-06		yes
Belgium	1996-11-22	2011-09-20		yes
Brazil	1994-02-28	2011-02-02		yes
Cambodia	1995-02-09	2012-02-01		yes
China	1993-01-05			
Denmark	1993-12-21	2011-06-23		yes
France	1994-07-01	2011-09-20		yes
Germany	1993-12-21	2011-06-23		yes
India	1994-02-18	2011-05-11	2012-10-09	yes
Indonesia	1994-08-23	2011-05-11		yes
Italy	1994-04-15	2011-06-23		yes
Japan	1993-05-28	2011-05-11		
Malaysia	1994-06-24			yes
Maldives	1992-11-09			yes
Myanmar	1994-11-25			yes
Netherlands	1994-07-12	2011-06-23		yes
Norway	1993-07-09	2011-05-11		yes
Pakistan	1994-07-26			yes
Papua-New-Guinea	1993-03-16			
Philippines	1993-10-08			yes
Poland	1996-01-18	2011-09-20		yes
Portugal	1993-12-21	2011-09-20		yes
Republic of Korea	1994-10-03	2011-09-20		yes
Democratic People's Republic of Korea	1994-10-26			yes
Lao People's Democratic Republic	1996-09-20		2012-09-26	yes
Singapore	1995-12-21			
Spain	1993-12-21	2011-07-21		yes
Sri Lanka	1994-03-23			
Sweden	1993-12-16	2011-06-23		yes
Thailand	2004-01-29	2012-01-31		only signed
United Kingdom	1994-06-03	2011-06-23		yes
Viet Nam	1994-11-16			
European Union	1993-12-21	2011-06-23		yes
USA	only signed			only signed

ADVANTAGES AND RISKS

- **Advantages to adopt ABS in the MTA**
  - Legality of the exchanges (security)
  - Traceability
  - Capacity to obtain international Certificate of Origin to publish the results, to deposit IPR, to develop the results…
  - Share knowledge
  - Ethics

ADVANTAGES AND RISKS

- **Risks to not adopt ABS**
  - Impossibility to develop the results
  - Hurts the reputation (affects partners confidence)
  - Legal sanctions:
    - fines,
    - imprisonment,
    - obligation to stop the activity or to destroy the GR

GLOBAL CONTEXT

- Research is a long process
- Results are uncertain
- Research is based on knowledge sharing
- Research needs a lot of GR (e.g., in Plants) and it’s not easy to determinate the participation of each GR in the final product.

NATIONAL REGULATION

- Countries with official free access to GR: Switzerland, Germany…

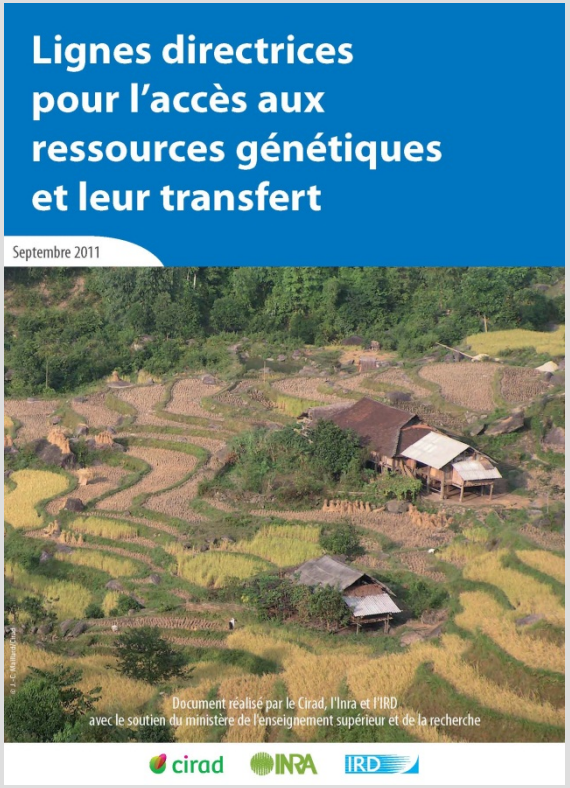
- Countries with regulation:
  - India (with official MTA)
  - Brazil (with validation of CGEN for Brazilian GR and publication to the Official Journal for exchange with Embrapa)

NATIONAL REGULATION

- Countries with regulation (continue):
  - Thailand: Chapters IV and V of the Plant Varieties Protection Act (1999), with distinction between research for commercial / non commercial purpose
  - EU: Regulation in 2014 (due diligence and trusted collections) but application in legislation by Member State
  - France: law in 2014

APPLICATION FOR MTA

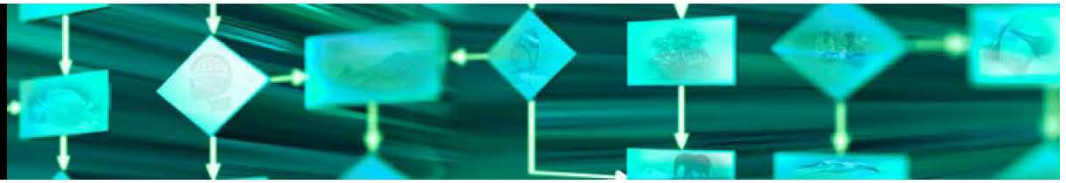
- CIRAD, INRA and IRD adopted voluntary rules for access and transfer of GR that are now a reference in France
- If the GR are included in the ITPGRFA, and the utilization of the GR is for food and agriculture use the SMTA



APPLICATION FOR MTA

- If not, contact the National Focal Point to know the national procedures and legislation:
  - List of National Focal Points
- Negotiate with the supplier or the recipient the conditions of ABS for the utilization of the GR or TK and includes the MAT in the MTA.
- Sometimes the MTA has to be validated by official service (e.g. Brazil for national GR)

Information



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> Information > Lists of NFPs

Lists of National Focal Points

National Focal Points of the Convention on Biological Diversity

- A training module has been prepared as part of the effort to enhance the capacity of the National Focal Points (NFPs) of Convention. The module introduces the Terms of Reference that were adopted at COP 8 and provides a brief description of the role of the NFP in practical terms. Click here to access this module.
- Please visit the Country Profiles to view national contacts by country.

Convention on Biological Diversity

- Primary National Focal Points to the Convention on Biological Diversity (CBD NFP)
- National Focal Points to the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA NFP)
- National Focal Points to the Clearing-House Mechanism (CHM NFP)
- National Focal Points to the Intergovernmental Committee for the Nagoya Protocol on Access and Benefit-sharing (ICNP ABS NFP)
- Competent National Authorities on Access and Benefit Sharing (ABS CNA)
- National Focal Points to the Global Taxonomy Initiative (GTI NFP)
- National Focal Points to the Global Strategy for Plant Conservation (GSPC NFP)
- National Focal Points to the Programme of Work on Protected Areas (PoWPA)
- National Focal Point for Article 8(j) and related provisions (Traditional knowledge and Customary Sustainable Use)

Cartagena Protocol on Biosafety

- Primary National Focal Point to the Cartagena Protocol on Biosafety (CPB NFP)
- National Focal Point to the Biosafety Clearing-House (BCH NFP)

MTA IS A CONTRACT

- Agreement between supplier (in most cases who has the GR) and the recipient (in most cases who will use the GR)
- A tool for traceability, CBD conformity
- Clarify the relationship with the possessors of GR and TK

MTA IS NOT

- A contract for sale GR or TK
- A licensing agreement
- An administrative authorization
- Valid for Cites (Convention on International Trade in Endangered Species of Wild Fauna and Flora) or phytosanitary/health requirements.

EXAMPLE OF MTA

- In case of research collaboration, the MTA is paired with the collaboration agreement.
- If the GR were received with a contract or MTA, the new MTA has to contain the conditions imposed by the initial MTA

EXAMPLE OF MTA

The Material is supplied by the Supplier to the Recipient under the following conditions:

TABLE 1. DESIGNATION OF PARTIES	
Supplier:	**Recipient:**
Registered Office:	Registered Office:
Represented by:	Represented by:
In his/her capacity as:	In his/her capacity as:
Acting on its behalf and on behalf of:	Acting on its behalf and on behalf of:
Represented by:	Represented by:
In his/her capacity as:	In his/her capacity as:
Legal address:	Legal address:

EXAMPLE OF MTA

TABLE 2: DESIGNATION OF MATERIAL	
Description of the material (the "Material") The material may be accompanied by information whose transmission and use are governed by rules expressed in the consortium agreement associated with this agreement.	- Designation of biological material: (common name)_____ ☐ Described in annex attached hereto: _____ ☐ Referenced by number (valid for CRB):____ - Designation of data and associated information: ☐ Traditional knowledge ☐ Confidential information ☐ Non-confidential information - Transfer includes access to a database: ☐ Yes ☐ No - Designation of Supplier centre: • Name (CRB, etc.): _____ • Address: _____
Identification of Material: A detailed Annex shall list the material if necessary (several entries)	Collection date: _____ Country of origin: _____ Initial Supplier (if from collection): _____ If IPR (Patent, PVP, Database…), precise reference :_____

TABLE 3. AUTHORIZED USE

The Material is transferred from the Supplier to the Recipient for the sole purpose of conducting research as described in the collaboration agreement specified:	Collaboration agreement: Research Project:
In order to conduct the project, the Recipient is authorised to use the Material in accordance with these defined processes, for the duration and in the locations specified below. **Any use of the Material apart from the "intended processes" is prohibited and can give rise to no claim on the part of the Recipient.** **In particular, the generic quality of the intended processes shall in no way authorise the use of the Material for purposes other than those expressly stipulated in the collaboration agreement.**	**Intended processes (*specify the authorized operations):*** ☐ **Any use authorized (Material freely accessible)** **1) Genetic modification:** Development of new variations within non-human species by means of genetic modification techniques, particularly: ☐ Transfer of a genetic characteristic ☐ Genetic modification of a microorganism ☐ Production of recombinant cell lines of attenuated vaccines ☐ Production of transgenic organism ☐ Use of nucleic acid-based techniques ☐ Use of cell fusion outside of the taxonomic family **2) Biosynthesis** ☐ Use of genetic material as factory for the production of organic compounds **3) Breeding and Domestication:** Creation of new varieties, strains or stem cell lines of non-human species, as: ☐ Breeding of plants, animals or microorganisms (crossing, artificial insemination, cloning…) ☐ Domestication from wild species **4) Propagation and culture of the genetic resource in its natural form:** ☐ Cultivation of microorganisms or plants ☐ Propagation of animals ☐ Production of plant, animal and microbial products ☐ Biocontrol. **5) Characterisation and assessment** ☐ Taxonomic Identification ☐ Phenotyping ☐ Genotyping ☐ Sequencing of genes or genomes ☐ Determination of the phenotype characteristics for other studies ☐ Experimental assessment of hereditary characteristics ☐ Isolation of a compound of genetic material for characterisation **6) Conservation:** Preservation of organisms for the conservation of genetic diversity: ☐ Collection, botanical gardens, zoos, aquariums, museum… ☐ Enrichment of natural forest **7) Other: _____**

EXAMPLE OF MTA

Duration:

The intended uses of the Material are limited to the duration of the agreement to which this MTA is annexed.
The intended uses of the Material are limited to ___ years after the date of signature of this MTA.

In case of extension of the collaboration agreement, this MTA will be extended under the same conditions.
All use of the Material apart from these terms will be subject to the prior written agreement of the Supplier.
The duration limit does not apply to Conservation operations.

If transfer of confidential information, the duration of confidentiality is ____ years

Location:

Designation: _____
Address: _____
Under the responsibility of: _____

TABLE 4. SHARING OF ADVANTAGES

To ensure the sharing of benefits with the country of the Material Supplier in accordance with the CBD, adopted on 22 May 1992 and entered into force on 29 December 1993, the Nagoya Protocol adopted on October 29, 2010, the Parties agree to make every effort to ensure the traceability of materials and compliance with prior informed consent of the Supplier of the Material.

If the Parties were to be led to use the Material or the Results for purposes of commercial exploitation, they shall negotiate in good faith the conditions of such exploitation, prior to any commercial use, in a monetary or non-monetary form, including Intellectual Property Rights sharing.

For purposes of sharing advantages, the Supplier and the Recipient have agreed to conduct research jointly as stipulated in the collaboration agreement to which this MTA is annexed.

The Recipient agrees to (tick the boxes):	☐ Limit access to the Material and associated information to only the partners of the collaboration agreement. ☐ Inform the Supplier of all later transfers and give the Supplier all elements in the Recipient's possession to ensure the traceability of the Material. ☐ Mention the origin of the Material and the identity of the Supplier in all publication of results issuing from the Study, except if contrary request of the Supplier. ☐ Transmit the research reports to the Supplier as required in the collaboration agreement ☐ Cite as co-authors the researcher nationals of the country of the Initial Supplier who have collaborated in the research. ☐ Provide access on request by the Initial Supplier to all non-confidential information obtained or collected by the Recipient. ☐ Availability of results to the Supplier under privileged conditions.
The Recipient agrees to respect the specific conditions mentioned against, including those raised by the Initial Supplier of the Material (precise in writing):	• Commitments made by the initial Supplier: _____ • Specific obligations: *(e.g., the Recipient cannot use the Material to produce GMO)*_____

EXAMPLE OF MTA

TABLE 5. TARIFF RATES
The Material is transmitted: ☐ At no charge ☐ In exchange for the sum of _____ € as reimbursement for preparation and shipping fees. In this case, the Supplier will send an invoice detailing payment methods (due date, amount), to the address listed on the first page of this document to the attention of the Recipient or of another person expressly designated.

EXAMPLE OF MTA

General Conditions

- **Definition**
  - **Study:** All research performed completely or in part using the Material and within the limits of use described in the collaboration agreement.
  - **Material**: The Material refers to the description of same in Table 2 and to certain elements directly issuing therefrom, such as progeny or descendants, mutants, variants and derivatives. It includes the Traditional Knowledge and all data associated.
  - **Derivatives**: Created substances constituting a functional, non-modified sub-unit (e.g., purified or fractionated parts of the original material, etc.)
  - **Product**: Any new substance created through the modification of the original Material by human intervention.
  - **Result**: Any product or knowledge obtained from the authorized use of the Material.

EXAMPLE OF MTA

- **Use of the Material**
  - The Material is transferred from the Supplier to the Recipient **for the sole purpose of use in conformity with the declarations executed in Table 3**. In case of uses not in conformity with those authorised, the Recipient shall return to the Supplier the resulting Products as well as any associated information, and may claim no right nor profit therefrom in any manner whatsoever.
  - **The Material may not be protected by any intellectual property rights on the received form whatsoever by the Recipient or any third party**.

EXAMPLE OF MTA

- **Later Transfer of Material by the Recipient:**

  yes (conditions) or no

- **Rights and obligations of the Recipient**
- **Warranties and Obligations of the Supplier**
- **Confidentiality** *(next slide)*
- **Term and Termination**
- **Applicable Law and Jurisdiction**

EXAMPLE OF MTA

- **Confidentiality**

With Research Collaboration: detailed in the Collaboration Agreement

Without Research Collaboration:

In case of transfer of confidential information, the Recipient agrees, unless otherwise consented in writing by the Supplier, to do the following:

- consider the Confidential Information strictly confidential and treat it with the same degree of protection it grants its own Confidential Information;
- not use the Confidential Information for purposes other than performance of the Research Project;
- not disclose the Confidential Information to third parties;
- transmit the Confidential Information under its responsibility only to employees or subcontractors who are directly concerned by the Research Project, themselves subject to contractual or statutory confidentiality.

Is not considered as confidential the information for which the Recipient that has received it can prove that:

- it belonged to the public domain at the time it was communicated; or
- it subsequently entered the public domain otherwise than by failure to meet the present obligation of confidentiality; or
- the Recipient held it prior to its being communicated, it being possible to prove this prior holding through the existence of appropriate documents in its files; or
- it was developed independently by one or more members of the personnel of the Recipient not having had access to said information; or
- the Recipient received it freely from a third party which is authorized to disclose it; or
- it is bound by the law or regulations to communicate said information or by an injunction of any competent administrative or judicial authority.

However, the Supplier cannot prevent publication of the Results, the filing of industrial property rights and exploitation of the Results, except for serious and legitimate reasons.

EXAMPLE OF MTA

This MTA and the collaboration agreement to which it is attached are inseparable. Regarding the **sharing of results** related to utilisation of the Material, **the publications** resulting from it, or the **confidentiality** related to transfer of the Material and its associated information, the terms of the abovementioned collaboration agreement are directly applicable to this MTA.

Signed and delivered in _____, in __ original copies.

On behalf of the Supplier
Title:
Name:
Date:

On behalf of the Recipient
Title:
Name:
Date:

MTA & IPR

- MTA respects the IPR on the Material
- Ownership and IPR on results:
  - Held by the Collaboration Agreement:
    - Co-ownership, common IPR, co-development and co-publication justified only if collaboration. The parties have to participate to obtain the results;
    - But, sharing of advantages is essential in any cases.
  - If there is no collaboration, IPR on results depends on the importance of the material to obtain the results:
    - If the material is fundamental to obtain the results co-ownership and co-IPR could be legitimated but not automatically
    - If the material is ordinary or another Institution could transfer the same material, co-ownership, co-IPR are not justified
    - In any case, if there is no collaboration, the co-publication is not allowed.

CONCLUSION

- MTA is:
  - A response to legal obligation in more and more countries
  - Important for security of access and exchanges (legally, for development of results, publications…)
  - A tool for research collaboration
  - A tool for confidence (with partners, Governments, official services, branding…)
  - An element of the Development by the Research

Thanks a lot
for
your attention